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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,703	12/12/2005	Carmelo Militello	117163.00130	6534
21324 7590 06/06/2007 HAHN LOESER & PARKS, LLP One GOJO Plaza Suite 300 AKRON, OH 44311-1076			EXAMINER FLORY, CHRISTOPHER A	
			ART UNIT 3762	PAPER NUMBER
			NOTIFICATION DATE 06/06/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/537,703	Applicant(s) MILITELLO, CARMELO	
	Examiner Christopher A. Flory	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-21 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/02/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1 recites the limitations "the intercardiac impedance" in line 10 and "the univentricular or biventricular stimulation mode" in line 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dal Molin et al. (US 6,556,866, hereinafter Molin'866).

Regarding claims 1, 3 and 4, Molin'866 discloses a cardiac pacemaker that inherently comprises a pulse generator since it is disclosed as delivering stimulation pulses (ABSTRACT), the pulse generator adapted for biventricular stimulation of the heart and connected to at least one right-ventricular electrode and one left-ventricular electrode (ABSTRACT; Fig. 1; column 2, lines 57-65); a control unit adapted for stimulation of the ventricles with an adjustable interventricular delay (ABSTRACT; column 1, lines 60-64; column 2, lines 8-16; column 4, lines 66-67); wherein the control unit is connected to an impedance detection unit (column 2, lines 18-24) adapted to be connected to a plurality of intercardiac electrodes (column 4, lines 9-15) and adapted to form from an input signal dependent on the intracardiac impedance an output signal indicating an optimum biventricular stimulation mode and adapted to adjust the optimum interventricular delay time (ABSTRACT; column 1, lines 60-65; column 2, lines 8-16).

Regarding claims 2 and 6, Molin'866 is considered to disclose various biventricular stimulation modes since it discloses stimulation at various cardiac sites with a plurality of selectable electrodes that are delivered with a varying interventricular delay time (column 2, lines 57-67; column 3, lines 12-31; column 4, lines 9-15).

Regarding claim 5, Molin'866 discloses that the interventricular delay can be selected to be zero milliseconds and as great as 48ms. Therefore, Molin'866 is considered to disclose a delay time adjustable between 20 and 40ms.

Regarding claims 8-10, Molin'866 discloses producing a current between a pacemaker housing and intracardiac electrode for impedance measurement, as well as detecting impedance by way of voltage (column 2, lines 25-29; column 3, lines 46-53;

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column 4, lines 51-57) wherein the electrodes for voltage measurement can be different from those producing the current for impedance measurement (column 4, lines 9-16).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molin'866.

Regarding claim 11, Molin'866 discloses the invention substantially as claimed, but does not explicitly disclose that the current strength is between 100 and 500 μ A. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a current strength between 100 and 500 μ A, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Regarding claim 12, Molin'866 discloses the invention substantially as claimed, but does not explicitly disclose that the pulse produced is a bi-phasic pulse. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Molin'866 system with a biphasic pulse because biphasic pulse patterns are

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widely known and used in the implantable stimulation art because biphasic pulses are known to reduce or eliminate charge buildup in the stimulated tissue that can be produced by repetitious monophasic stimuli.

Regarding claim 13, Molin'866 discloses the invention substantially as claimed, but does not explicitly disclose a pulse frequency between 100 and 150 Hz. It would have been obvious to one having ordinary skill in the art at the time of the invention to stimulate using a frequency of 100 to 150 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Regarding claim 14, Molin'866 discloses the invention substantially as claimed, but does not explicitly disclose a pulse duration of 20 to 40 μ s. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a pulse duration of 20-40 μ s, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Regarding claim 15, Molin'866 discloses the invention substantially as claimed, but does not expressly disclose that the control unit is adapted to average the impedance in the time window between 50 and 300ms in duration. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an

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average impedance signal because it is well known in the cardiac sensing art that using average variable values eliminates beat-to-beat variations of the heart signal to deliver more accurate therapies. Furthermore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a time window of 50 to 300 ms to span several heart cycles in order to obtain this average, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Regarding claim 16, Molin'866 discloses the invention substantially as claimed but does not disclose expressly beginning the time window with detection of a left-ventricular event. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Molin'866 with the starting the time window on a left-ventricular event, because Applicant has not disclosed that starting with a left-ventricular event provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with starting the time window at any other point within the cardiac cycle, e.g. with a sensed right-ventricular event, because it provides an initial time t_0 for averaging the impedance value and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Molin'866

Therefore, it would have been an obvious matter of design choice to modify the system of Molin'866 to obtain the invention as specified in the claim(s).

Regarding claim 17, Molin'866 is considered to inherently calculate an impedance pattern since it uses real-time updated impedance data to automatically optimize a therapy pattern.

Regarding claim 18, Molin'866 discloses measuring the maximum impedance during one cardiac cycle, as well as the spacing in respect to time between the QRS complex and the maximum and minimum intracardiac impedances (column 4, lines 58-65; Fig. 2).

Regarding claim 19, Molin'866 shows a dual-chamber pacemaker with at least one ventricular and one atrial detection unit (Fig. 1).

Regarding claims 20 and 21, the pacemaker disclosed in Molin'866 is considered rate-adaptive since it adjusts the timing with which biventricular stimulation is delivered based on a changing measured intracardiac impedance variable (ABSTRACT).

Allowable Subject Matter

9. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

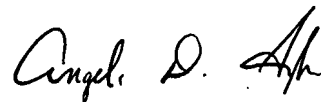
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
16 May 2007

George Manuel
Primary Examiner



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